REMARKS / ARGUMENTS

Claims 17-18 and 21-41 are pending in this application.

Rejections under 35 U.S.C. §112

The Examiner has rejected claims 17, 18 and 21-41 under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement. Specifically, the Examiner alleges that the specification does not disclose methods of treating both HBV and HIV. The Examiner acknowledges that the specification describes methods of treating HBV, and that the specification provides the following disclosure on page 6: "In light of the fact that HBV is often found in patients who are also anti-HIV antibody or HIV-antigen positive or who have been exposed to HIV, the active anti-HBV compounds disclosed herein or their derivatives or prodrugs can be administered in the appropriate circumstance in combination or alternation with anti-HIV medications".

The Examiner further contends that "the original disclosure does not have support for the method presently claimed." Specifically, the Examiner asserts that "the fact that patients also may be anti-HIV antibody or HIV-antigen positive, is not seen to clearly support the claimed methods of treating both HIV and HBV."

It is respectfully submitted that the Examiner has misread the claims. Claim 1 recites: "A method of treating a patient infected with hepatitis B virus and HIV comprising administering to the patient a nucleotide prodrug of β-L-2',3'-dideoxyadenosine (β-L-DDA) in combination with a second compound selected from:

a) 3'-azido-3'-deoxythymidine (AZT),

b) 2',3'-dideoxyinosine (DDI),

c) 2',3'-dideoxy-2',3'-didehydrothymidine (D4T),

d) 2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane (FTC),

e) a Tibo compound, nevirapine, or a pyrimidinone, or

f) a physiologically acceptable salt thereof.

Claim 1 does not state that nucleotide prodrugs of β-L-DDA are being used to treat HBV and HIV. The combination of β-L-DDA and an anti-HIV agent is provided for treatment of a patient infected with HBV and HIV. β-L-DDA has been shown to have anti-HBV activity and is provided in this method to treat the HBV infection in that patient. Thus, the nucleotide prodrug of β-L-DDA is targeted at the hepatitis B virus, while the second compound is targeted at HIV. As discussed in the Response to Office Action mailed July 27, 2006, the "second compound" recited in the claims is selected from a list of pharmaceutical agents which are derived from those listed in the specification on page 6, lines 18-28, and these compounds are known for their use in the treatment of patients infected with HIV. Thus, the anti-HIV activity of these compounds is already established. Furthermore, the anti-HIV agents provided for use in the combination therapy disclosed in the specification have been used in combination with other nucleosides. Phosphorylated derivatives of β-L-DDA are not likely to have a physicochemical interaction with other nucleosides or the second compounds recited in the amended claims.

Furthermore, Applicants respectfully disagree with the Examiner's contention that the specification does not disclose methods of treating both HBV and HIV. The amended claims are limited to methods and pharmaceutical compositions of nucleotide prodrugs of β-L-DDA in combination with selected anti-HIV agents for the treatment of a patient infected with HBV and HIV. As discussed in the Response to Office Action mailed July 26, 2007, the preparation, anti-HBV activity, cytotoxicity and selectivity of nucleotide prodrugs of β-L-DDA is disclosed in the specification on pages 18-29 and 35-36. That the nucleotide prodrugs of β-L-DDA can be administered in combination with selected anti-HIV medications for the treatment of patients infected with both HBV and HIV is specifically disclosed in the specification on page 6, lines 18-28. Preparation of pharmaceutical compositions comprising the nucleotide prodrugs is described on pages 37-41. In particular, it is stated in the specification that "the active compound is administered as described in the product insert or Physician's Desk Reference for 3'-

azido-3'-deoxythymidine (AZT), 2',3'-dideoxyinosine (DDI), 2',3'-dideoxycytidine (DDC), or 2',3'-dideoxy-2',3'-didehydrothymidine (D4T) for HIV indication (page 38, lines 11-14)." Notably, these compounds indicated for HIV are several of those indicated for use in combination therapy for the nucleotide prodrugs of β-L-DDA. That these compounds can be administered in the same manner adds significantly to their ease of use in combination therapy. Furthermore, on page 40, it is stated in the specification that the active compounds can be mixed with other active materials that do not impair the desired action, such as other antivirals, including anti-HIV agents.

Further to this, even the Background of the Invention section establishes that HBV and HIV commonly infect the same patient. The specification states that "the epidemiology of HBV is in fact very similar to that of acquired immunodeficiency syndrome, which accounts for why HBV infection is common among patients with AIDS or HIV-associated infections." (page 2, lines 2-4.) The specification also references a few publications regarding nucleosides that are useful for treatment of both HBV and HIV (page 2, lines 13-25). It is further disclosed that "an essential step in the mode of action of purine and pyrimidine nucleosides against viral diseases, and in particular, HBV and HIV, is their metabolic activation by cellular and viral kinases, to yield the mono-, di-, and triphosphate derivatives" (page 2, lines 26-28). Thus, the specification immediately sets forth the target patient population for the methods of treatment, which includes those that are HBV and HIV coinfected.

Thus, there is clear support for the claimed method of treating a patient infected with HBV and HIV comprising administering to the patient a nucleotide prodrug of β-L-DDA in combination with selected second compounds. Applicants submit that one of skill in the art would have been able to make and use the invention from the specification as originally filed. Withdrawal of this rejection is respectfully requested.

Applicants respectfully request consideration of the remarks and withdrawal of the outstanding rejection in this matter. A Credit Card Payment Form is included for

payment of the required fees, however, the Commissioner for Patents is authorized to charge any deficiencies associated with this Response, or credit any overpayment, to Deposit Account No. 11-0980.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this Amendment and Response to Office Action along with any documents referred to as attached therein are being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **March 20, 2008**.

Nicole Smythe